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Pesticide Fact Sheet No. 217: 'Gliocladium virens' GL-21

(U.S.) Environmental Protection Agency, Washington, DC

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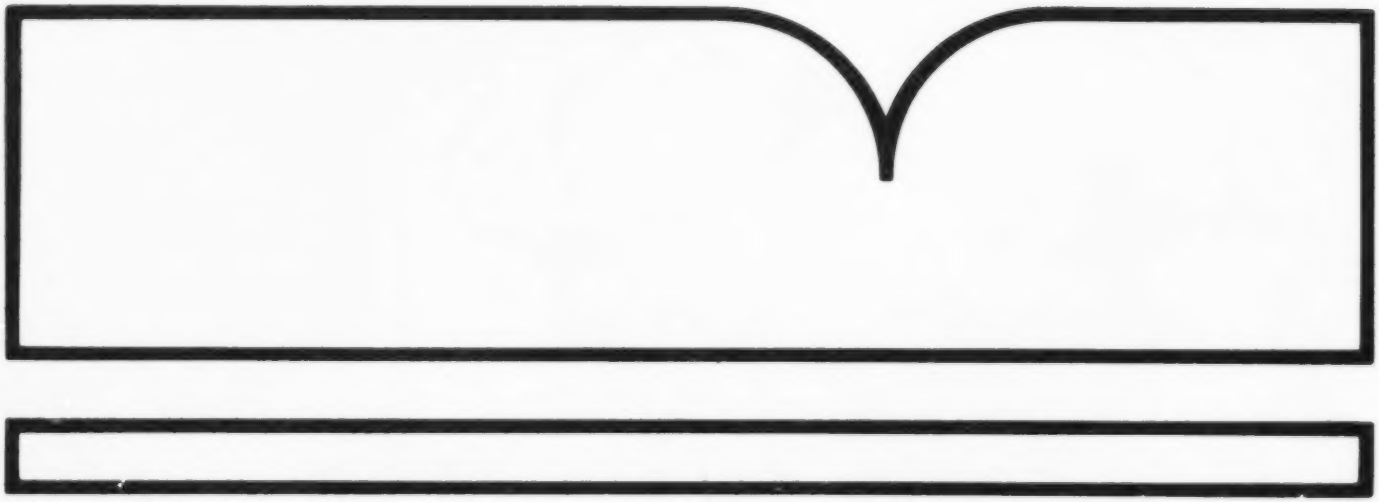

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13. Type of Report & Period Covered

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15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on ~~a specific~~ pesticide ~~or~~ group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred:

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:	19. Security Class (This Report)	21. No. of Pages
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EPA

Pesticide Fact Sheet

Name of Chemical: Gliocladium virens GL-21
Reason for Issuance: Registration of New Biological Pesticide
Date Issued: November 1990
Fact Sheet Number: 217

1. Description

Generic Name:	Gliocladium virens GL-21
Trade Names:	WRC-GL-21 and WRC-AP-1
EPA Shaughnessy Code:	128900-8
Year of Initial Registration:	1990
Pesticide Type:	Biofungicide
U.S. and Foreign Producers:	W.R. Grace & Co. 7379 Route 32 Columbia, MD 21044

2. Use Patterns and Formulations

Application sites: The manufacturing use product (MP) is for use only in the formulation of fungicides. The end-use product (EP) is for use in the control of damping-off diseases, particularly those caused by Pythium and Rhizoctonia, of greenhouse ornamental and food crops.

Types of formulations: A liquid MP containing 20% active ingredient and a granular EP containing 12% active ingredient.

Types and methods of application: The EP is blended with soil or soilless plant growing media at least 3 days prior to planting or incorporated into the media surface in plant beds prior to or at planting.

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invertebrates, estuarine and marine animals, non-target insects and honey bees were either not required or waived based on the nature of the product and its proposed use pattern. Since there will be minimal exposure to non-target organisms from the use of this product in greenhouse food and non-food crops, there is not expected to be a "may effect" situation with regard to endangered species.

Data for environmental fate (Tier II) are not required for this biofungicide since there will be negligible environmental exposure associated with the use in greenhouses and the initial (Tier I) tests were waived or not required.

Chemical Characteristics:

Property	MP	EP
Color	Tan to brown	Tan to brown
Physical state	Slurry	1mm Spherical beads
Odor	Slight molasses	Slight molasses
Density/bulk density	1.1 g/l	0.66 g/l
pH	6.7-7.0	5-6
Stability	Stable	Not required
Storage stability	30 d at 10°C	300 d at 25°C
Viscosity	4.5 cp	N/A
Miscibility	N/A	N/A
Corrosion characteristic	Not corrosive to intended plastic containers	Not corrosive to intended plastic containers

Toxicological Characteristics:

Acute effects: Data were submitted for acute toxicity/pathogenicity as determined in oral, pulmonary and intravenous tests. Data were classified acceptable.

Other toxicity testing: Additional toxicity testing was waived based upon submission or availability of data or information which:

1. indicated that the fungus does not grow at or near the body temperature of mammals or birds,
2. demonstrated that toxins or antibiotics which were produced during the manufacture of the product were not considered to be of toxicological significance,
3. showed that personnel working with Gliocladium virens strain GL-21 for 1-2 years evidenced no adverse toxicological effects attributable to that work,
4. provides the criteria used to determine the extent to which formulated preparations are free from contaminating microorganisms, and
5. confirmed the exempt status of certain inert ingredients.

Application rate: The EP is applied at the rate of 1 - 1 1/4 ounces/cubic foot of media when blended or at the rate of 3/4 - 1 ounce/square foot of bed surface.

3. Science Findings

Summary Science Statement:

The toxicological data which were submitted for this active ingredient included reports of an acute oral toxicity/pathogenicity study, an acute pulmonary toxicity/pathogenicity study and an acute intravenous toxicity/pathogenicity study. The studies were performed using rats. All studies were classified as acceptable. The review of these studies indicates that the biofungicide is not toxic to, infective in, or pathogenic to rats by oral or pulmonary routes of exposure and not infective or pathogenic to rats by intravenous injection. Mycelium of the fungus was used for the injections and was found to be acutely toxic and lethal to test animals due to mechanical clogging of capillaries, however, these mortalities were not considered to be relevant in this case since injection is not a normal route of exposure and the product consists of chlamydospores rather than mycelium.

Acute dermal toxicity testing was not required for this biofungicide based on the facts that the end-use product consists of large pellets, the label will require that gloves be worn when handling the product and application will be by soil incorporation. A primary eye irritation study was not required since protective eye covering must be worn. The inert materials in the product have been exempted from the requirement for a tolerance in §180.1001 and no indications of toxicity were reported in workers following 1-2 years of working with the organism.

Although Gliocladium strains are known to produce certain toxins, data were submitted which showed that only one of the known toxins (gliotoxin) was produced in detectable amounts. Since gliotoxin is sensitive to oxidation, the levels that may exist in the product are not considered to be of toxicological significance since the toxin will be rapidly degraded. This conclusion is supported by the demonstrated lack of toxicity in the oral and pulmonary studies conducted on rats.

Data requirements for evaluating adverse effects on birds, wild mammals, freshwater fish, freshwater aquatic

Ecological Effects:

Data on the ecological effects of the biofungicide were waived based upon information demonstrating that the fungus will not grow at or near body temperatures of mammals or birds, that the fungus is ubiquitous in nature and that the use patterns are unlikely to result in additional exposure of aquatic organisms or other non-target wildlife of ecological concern.

4. Benefits

The use of the end-use product will be beneficial in the control of damping-off diseases of seedling plants which is a major source of economic loss in the greenhouse production of ornamental and food-crop plants. The availability of a biological fungicide would provide a less toxic alternative to the currently registered chemical treatments.

5. Tolerance Assessment:

An exemption from the requirement for a tolerance for residues of Gliocladium virens GL-21 in or on all raw agricultural commodities when used as a fungicide for inoculation of plant growth media in greenhouses in accordance with good agricultural practices was submitted. Since testing of the biofungicide showed no evidence of effects which would be of toxicological concern, an exemption will be granted.

6. Summary of Major Data Gaps:

No data gaps exist for this active ingredient.

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